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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/544,045      04/06/00      SAUER

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HM22/1001

EXAMINER

SANDALS.W

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

10/01/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/544,045

Applicant(s)  
Sauer et al.

Examiner  
William Sandals

Art Unit  
1636



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 26, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-63 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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**DETAILED ACTION**

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-49 and 53, drawn to a method of identifying variant recombinases and their variant recombination sites, and to a method of producing site specific recombination with variant recombinases, classified in class 435, subclass 6.
  - II. Claims 50 and 51, drawn to a method of cloning large DNA fragments with concatemers, with a variant recombinase, classified in class 435, subclass 462.
  - III. Claim 52, drawn to a method of cloning large DNA fragments without concatemers, with a variant recombinase, classified in class 435, subclass 462.
  - IV. Claim 53, drawn to a variant recombinase, classified in class 530, subclass 350.
  - V. Claims 54-57, drawn to a nucleic acid encoding a variant recombinase and a cell containing the nucleic acid, classified in class 536, subclass 23.1.
  - VI. Claims 57 and 58, drawn to a transgenic plant, animal or mammal, classified in class 800, subclass 8.
  - VII. Claims 59-63, drawn to a nucleic acid encoding a recombination site and a cell containing the nucleic acid, classified in class 536, subclass 23.1.

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2. Groups V and VI each contain claim 57 in common. Claim 57 contains subject matter which comprises multiple inventions. Should either Group V or Group VI be elected, claim 57 will be examined only as it pertains to the subject matter of the elected group.
3. The inventions are distinct, each from the other because of the following reasons:
4. The inventions of Groups I-III are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of each of the Groups I-III comprise steps which are not required for nor present in the methods of each of the other Groups I-III: identification of variant recombinases and variant recombinase sites (Group I), cloning of large DNA concatemers (Group II), cloning of large DNA's which are not concatemers (Group III). The end result of the methods are different: identified variant recombinases and variant recombinase sites (Group I), cloned large DNA concatemers (Group II), cloned large DNA's which are not concatemers (Group III). Thus the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.
5. The inventions of Groups IV-VII are biologically, chemically structurally and functionally different from each other and thus one does not render the other obvious. The variant recombinase of Group IV is not required to produce the DNA of Group V, nor the transgenic plant or animal of Group VI, nor the nucleic acid encoding a variant recombination site of Group VII. Therefore, the inventions of the four groups are capable of supporting separate patents.

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6. Inventions of Groups I-III and Groups IV-VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the variant recombinase can be made by totally synthetic means, the nucleic acid encoding the variant recombinase can be made by totally synthetic means, the transgenic animal can be transfected with a nucleic acid which is identified by another method, such as a nucleic acid probe, and the nucleic acid encoding the recombination site can be made by totally synthetic means.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, also the non-patent literature search required for each of Groups I-VII is not required for each of the other Groups I-VII, therefore restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

### *Conclusion*

10. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Schwartzman can be reached at (703) 308-7307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.  
Examiner  
September 18, 2001

  
TERRY MCKELVEY  
PRIMARY EXAMINER